

**REMARKS**

The Office Action of March 14, 2011, has been received and reviewed. Claims 1 through 16 are currently pending in the application. Claims 1 through 16 stand rejected. Applicant has amended claim 16 to correct a typographical error. Applicant respectfully requests reconsideration of the application according to the remarks presented herein.

**Information Disclosure Statement(s)**

Applicant notes the filing of an Information Disclosure Statement on March 8, 2011, and note that no copy of the Form PTO/SB/08 was returned with the outstanding Office Action. Applicant respectfully requests that the information cited on the Form PTO/SB/08 be made of record herein. It has been verified that the Information Disclosure Statement of March 8, 2011, was filed and has been entered into the record as confirmed in the Image File Wrapper on PAIR as of May 5, 2011. It is respectfully requested that an initialed copy of the PTO/SB/08A evidencing consideration of the cited references be returned to the undersigned attorney.

**Interview Summary**

A telephone interview was held on March 10, 2011 with Examiners Larry Wilson and Theodore Stigell communicating for the USPTO, and Matthew Ward and Jeffrey Gunn communicating for the Applicant. Applicant would like to thank the Examiner for the courtesy extended during the telephone interview. The interview was very helpful to the Applicant and their representatives in gaining an understanding of the Examiner's concerns. At the interview, the rejections made in the Office Action of March 14, 2011 were discussed, as were the Examiner's and Applicant's perspectives with respect to the rejections. As discussed at the interview, the arguments discussed during the interview are submitted with this response, which the Examiner agreed to consider. If the Office believes that further comments are necessary or desired describing the interview, the Examiner is kindly requested to contact Applicant's undersigned attorney, and further detail will be promptly provided.

**35 U.S.C. § 103(a) Obviousness Rejections**

Obviousness Rejection Based on U.S. Patent No. 6,071,274 to Thompson et al., in view of U.S. Patent Publication No. 2001/0007070 to Stewart et al.

Claims 1 through 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Thompson et al. (U.S. Patent No. 6,071,274), in view of Stewart et al. (U.S. Patent Publication No. 2001/0007070). Applicant respectfully traverses this rejection, as hereinafter set forth.

To establish a *prima facie* case of obviousness, the prior art reference itself (or references when combined) or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention must teach or suggest all of the claim elements. *K.S.R. Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 U.S.P.Q.2d 1385 (2007); *see also* M.P.E.P. § 2143.03. Additionally, the Examiner must determine whether there is “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *Id.* “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* Further, rejections on obviousness grounds “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Finally, to establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Furthermore, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006); MPEP § 2144. Underlying the obvious determination is the fact that hindsight cannot be used. *KSR*, 550 U.S. at 421; *DyStar*, 464 F.3d at 1367.

Thompson and Stewart, when combined, do not teach, suggest, or otherwise render obvious independent claim 1. In particular, claim 1, recites, in part:

wherein, due, at least in part, to the anchoring of the distal end of the shape-imparting element to the introducer, the formation is adjusted in the plane substantially orthogonal to the longitudinal axis of the introducer in terms of an inner area

of the predetermined shape in the plane substantially orthogonal to the longitudinal axis of the introducer, when torsion is applied to the shape-imparting element.

In other words, an area-variable shape may be created in the distal end of the tubular member. The area-variable shape is in a plane substantially orthogonal to the longitudinal axis of the introducer. Such an area-variable shape may be useful in terms of ablation, during which it may be possible to ablate a surface in front of the introducer, and control the size of the ablation area (for example, by varying the size of a loop).

Thompson teaches a structure 100 carrying multiple electrode elements 28. Structure 100 is carried at the distal end 16 of a flexible catheter tube 12, as a part of a probe 10, as shown in FIG. 1. *See also* Thompson, col. 13, lines 30-37. A sheath 102 is carried by the catheter tube 12, the sheath 102 including a distal section 104 extending about the multiple electrode structure 100. A short length of wire 106 is used to join the distal section 104 of the sheath 102 to the distal end 108 of the multiple electrode structure 100. *See* Thompson, col. 13, lines 45-57.

As shown in FIG. 15A, among other figures, Thompson teaches the formation of a loop in a plane extending parallel to the axis of the introducer, and not in a plane orthogonal to the longitudinal axis of the introducer. In addition, Thompson does not teach controlling the size of that shape in such an orthogonal plane. Instead, a loop is formed in the parallel plane by manipulating the catheter tube 12 to extend a member 20 out through a slot in a sheath 26. *See* Thompson, col. 10, lines 4-11. Thus, while Thompson teaches a structure 100 that allows the formation of a loop, Thompson only teaches that the area-variable shape is in a plane parallel to the axis of the introducer. For example, Thompson teaches that the underlying mechanics for forming the variable-sized loop is to provide a tube with a short length of wire 106 affixed at the end of the sheath 102. As a result, as the insert is pushed forward through the sheath 102, the insert bulges out of an aperture in the sheath 102, and forms an area-variable loop in a plane parallel to the axis of the sheath 102. Thompson does not teach or suggest that such a geometry of the loop can be adjusted in a plane substantially orthogonal to the longitudinal axis of the introducer.

Stewart teaches a catheter assembly 20 including a catheter body 22, a handle 24, and electrodes 26. Stewart, ¶ [0065]. Stewart further teaches:

The distal portion 32 extends from the intermediate portion 30 and forms a loop 34. In one preferred embodiment, the loop 34 is circular, formed in a plane transverse to the longitudinal axis L1. To this end, the distal portion 32 preferably includes a lateral segment 36. The lateral segment 36 extends in a generally lateral fashion from the intermediate portion 30. The loop 34 extends from the lateral segment 36 in an arcuate fashion, turning or revolving about a central loop axis C1 (shown best in FIG. 1B). Stewart, ¶ [0068].

While Stewart may teach a loop that is formed in a plane transverse to the longitudinal axis L1, as shown in FIGS. 1B and 1C, among other figures, the shape of the loop is fixed, and Stewart does not allow for shape control of the loop. In particular, Stewart teaches using shape memory alloys, such as Nitinol to be pre-formed during manufacture into a desired shape, such as a loop. *See* Stewart, ¶ [0071]. Such shape memory alloys are generally held in a linear configuration within a tube during introduction into the patient's body, whereupon the shape memory alloy is then pushed out of the end of the tube in order to adopt its desired shape. Stewart does not teach shape control via anchoring a shape-imparting element to an introducer, let alone any formation that may be adjusted in the plane substantially orthogonal of the introducer, by applying torsion to the shape-imparting element. Rather, Stewart teaches that the shape is not variable in size. For example, where the shape is a loop, the size of that loop is determined at the time of manufacture and is, therefore, not controllable.

Thus, Thompson and Stewart teach forming a loop at the end of a catheter assembly with significantly different approaches. Thompson teaches creating a variable loop by anchoring the distal end of a shape imparting element to the distal end of an introducer, allowing for a viable loop in a plane parallel to the axis of the introducer. Stewart teaches using a shape memory alloy that extends beyond the end of the introducer to create a fixed predefined shape in an axis orthogonal to that of the introducer. The shape memory alloy is not fixed to its introducer. Nor is any torsion applied to a shape-imparting element to adjust a formation in a plane substantially orthogonal to the longitudinal axis of the introducer, as is recited in claim 1.

In addition, Applicant respectfully asserts that a person of ordinary skill in the art would not combine the teachings of Thompson and Stewart to anchor a shape-imparting element to the distal end of an introducer. For example, if the shape memory alloy from Stewart were to be

used with the introducer of Thompson, such that the shape memory alloy were anchored to the distal end of that introducer, the desired shape of the shape memory alloy taught by Stewart would not be formed. In particular, anchoring a shape memory alloy that has been shaped according to the teachings of Stewart would cause the desired shape taught by Stewart to be warped during operation in an unpredictable manner. In other words, anchoring the shape memory alloy having an initial shape taught by Stewart, would prevent the shape memory alloy from adopting its intended shape, and instead would take a shape that is contrary to the teachings of Stewart. Therefore, Applicant respectfully asserts that a person of ordinary skill in the art would, therefore, not have a reason for combining the teachings of Thompson and Stewart, as doing so would result in a shape that would not result in a reasonable likelihood of success to arrive at the desired shape. Applicant respectfully notes that in order to avoid impermissible hindsight, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant's disclosure. *See* MPEP § 2144.

In summary, Applicant respectfully asserts that Thompson and Stewart do not teach, suggest, or otherwise render obvious all the limitations recited in independent claim 1. In addition, Applicant asserts that there is no reason to combine the references based on the teachings of Thompson and Stewart, because doing so would result in an unexpected, unpredictable shape that is contrary to the teachings of Thompson and Stewart. Therefore, independent claim 1 would not have been obvious to a person of ordinary skill in the art at the time the invention was made considering Thompson in view of Stewart. The Applicant respectfully requests that the Examiner withdraw the rejection of independent claim 1 under 35 U.S.C. § 103(a).

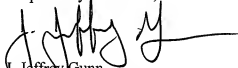
Furthermore, the nonobviousness of independent claim 1 precludes a rejection of claims 2 through 15, which depend therefrom, because a dependent claim is obvious only if the independent claim from which it depends is obvious. *See In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988), *see also* MPEP § 2143.03. Therefore, Applicant requests that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to claims 2 through 15, in addition to the rejection to independent claim 1.

Independent claim 16 recites subject matter similar to that of claim 1 and is proposed to be amended in a manner similar to that of claim 1. As a result, the analysis presented above with respect to claim 1 in view of Thompson and Stewart is also applicable to claim 16, which is therefore allowable. The Applicant respectfully requests that the Examiner withdraw the rejection of independent claim 16 under 35 U.S.C. § 103(a).

### CONCLUSION

Claims 1 through 16 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicant's undersigned attorney.

Respectfully submitted,



J. Jeffrey Gunn  
Registration No. 56,957  
Attorney for Applicant(s)  
TRASKBRITT  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

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JJG/nj:slm